This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Dornier MedTech America, Inc. 1155 Roberts Blvd. Kennesaw, GA 30144
Contact Person:	John Hoffer Vice President, Quality, Regulatory, Clinical
Phone Number:	770-514-6163
Fax Number:	770-514-6291
Establishment Registration Number:	1037955
Date Prepared:	September 27, 2011
Device Trade Name(s):	*Medilas D LiteBeam+ 1470*
Device Common Name:	Diode Laser System
Regulation Number:	21 CFR 878.4810
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class:	Class II
Product Code:	GEX
Predicate Device(s):	The *Dornier Medilas D LiteBeam+ 1470* is substantially equivalent to the Biolitic 15W Ceralas Diode 1470nm Laser (K073063).
General Device Description:	The Dornier *Medilas D Lite Beam + 1470 Laser* is a continuous-wave diode laser emitting laser radiation in the invisible range of 1470 nm. The *Medilas D LiteBeam+ 1470* incorporates a graphic display panel, which shows laser operating parameters, application modes, time functions, system status and messages for the user. The *Medilas D LiteBeam+ 1470* features several operating modes, including Standard, Fibertom and LPS.

Intended Use:	The Dornier Medilas D LiteBeam 1470 is a diode laser that is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is intended for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
Technological Characteristics:	From a clinical perspective and comparing design specifications, Dornier *Medilas D Lite Beam + 1470 Laser* and the predicate device is substantially equivalent. Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that no significant differences exist between the proposed diode laser and the predicate device. Dornier MedTech America, Inc. believes the minor differences of the Dornier *Medilas D Lite Beam + 1470 Laser* and its predicate laser should not raise any concerns regarding the overall safety or effectiveness.
Performance Data:	While no performance standards have been established for Diode lasers under Section 514 of the Federal Food, Drug, and Cosmetic Act, the Dornier Medilas D LiteBeam+ 1470 is in compliance with class IV performance standards for light emitting products promulgated under the Radiation Control for Health and Safety Act of 1968. See 21 C.F.R. §1040.10 and §1040.11. The laser also complies with the applicable requirements of the following voluntary standards: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-22, IEC 60825-1, and European Medical Device Directive (CE).
Conclusion:	Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that the Dornier *Medilas D Lite Beam + 1470 Laser* and the predicate device selected are substantially equivalent and that the differences between the devices are minor which do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 7 2011

Dornier MedTech America, Inc.
% Mr. John Hoffer
Vice President, Quality, Regulatory, Clinical
1156 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K110364
Trade/Device Name: Dornier Medilas D LiteBeam + 1470
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 02, 2011
Received: December 02, 2011

Dear Mr. Hoffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110364 pg 1 of 1

Device Name: Dornier Medilas D LiteBeam + 1470

Indications for Use:

The Dornier *Medilas D LiteBeam + 1470* is a diode laser that is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is intended for the treatment of reflux of saphenous veins associated with varicose veins and varicosities.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110364